

THE HUMANE SOCIETY OF THE UNITED STATES

OFFICERS

David O. Wiebers, M.D.
Chairman of the Board
Anita W. Coupe, Esq.
Vice Chairman
Amy Freeman Lee, Litt.D.
Secretary
Paul G. Irwin
President, CEO
G. Thomas Warte III
Treasurer, CFO
Patricia A. Forkan
Executive Vice President
Roger A. Kindorf, Esq.
Vice President/General Counsel

STAFF VICE PRESIDENTS

Martina C. Armstrong
*Senior Vice President
Companion Animals
and Equine Protection*
John W. Grauby, Ph.D.
*Senior Vice President
Wildlife Programs*
Wayne Pacane
*Senior Vice President
Communications and
Government Affairs*
Andrew N. Rowan, Ph.D.
*Senior Vice President
Research, Education, and
International Issues*
Michael C. Appleby, B.Sc., Ph.D.
*Farm Animals and
Sustainable Agriculture*
Katherine Benedict
*Administration, Information
Services, and Technology*
Richard M. Clapperton, Ph.D.
Higher Education
Randall Lockwood, Ph.D.
Research and Educational Outreach
Robert G. Roop, Ph.D., SPHR
Human Resources and Education
Melissa Scide Rubin, Esq.
Field and Disaster Services
Martin L. Stephens, Ph.D.
Animal Research Issues
Richard W. Swann Jr.
Investigative Services

DIRECTORS

Patricia Mares Asip
Peter A. Bender
Donald W. Cashen, Ph.D.
Anita W. Coupe, Esq.
Jack Friedman
Alice R. Garey
Jennifer Leasing, M.D.
Amy Freeman Lee, Litt.D.
Franklin M. Loew, D.V.M.
Eugene W. Lorenz
Jack W. Lydman
William F. Mancuso
Juan C. March-Brown
Patrick L. McDonnell
Judy J. Peil
Joe Ramsey, Esq.
Jeffery D. Rose
James D. Ross, Esq.
Marilyn G. Seyler
Maurice F. Strong, Ph.D., C.C., U.D.
John E. Tarr
David O. Wiebers, M.D.
Marilyn E. Winheim
K. William Wiseman
John A. Hoyt
President Emeritus
Murdaugh Stuart Madden, Esq.
Vice President/Senior Counsel

NGO in official consultative status
with the Economic and Social Council
of the United Nations
Printed on recycled paper

November 26, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Ln, Room 1061
Rockville, MD 20852

Docket No. 98D-1146, "Draft Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern"

These comments are submitted on behalf of The Humane Society of the United States, the country's largest animal protection organization, with more than seven million supporters nationwide. While we are concerned with the use of antimicrobials by agriculture because of its contribution to the growing health crisis of antibiotic resistance we would like to take this opportunity to voice our concern about their use in relation to animal welfare. We are deeply concerned about the use of antimicrobials in animal production, in particular their use at subtherapeutic levels. While we strongly support preventing disease in animals, there are better ways to accomplish this than by routinely feeding animals with low dosages of antimicrobials. Such usage has mainly arisen because of unacceptable aspects of intensive husbandry such as crowding, poor sanitation, and stressful conditions, all of which are detrimental to animal health and welfare.

Until calls for restrictions on antimicrobials led the agricultural industry to defend them as necessary for health care, subtherapeutic antimicrobials given to farm animals were generally referred to as 'growth promoters'. Promotion of growth by antimicrobials is firstly unnecessary and secondly evidence for inadequate husbandry and management. Crowded and unsanitary conditions increase the amount of pathogens that animals are exposed to and facilitate the spread of disease. The disease controlling effects of subtherapeutic levels of antimicrobials are less pronounced in clean, healthful, and stress-free environments and the

98D-1146

C 69

Promoting the protection of all animals

2100 L Street, NW, Washington, DC 20037 • 202-452-1100 • Fax: 202-778-6132 • www.hsus.org

THE HUMANE SOCIETY OF THE UNITED STATES

OFFICERS

David O. Wiebers, M.D.
Chairman of the Board
Anita W. Coupe, Esq.
Vice Chairman
Milly Freeman Lee, Litt. D.
Secretary
Paul G. Irwin
President, CEO
G. Thomas White III
Treasurer, CFO
Patricia A. Forkan
Executive Vice President
Roger A. Knödel, Esq.
Vice President/General Counsel

STAFF VICE PRESIDENTS

Martina C. Armstrong
*Senior Vice President
Companion Animals
and Equine Protection*
John W. Grandy, Ph.D.
*Senior Vice President
Wildlife Programs*
Wayne Paszala
*Senior Vice President
Communications and
Government Affairs*
Andrew N. Rowan, Ph.D.
*Senior Vice President
Research Education and
International Issues*
Michael C. Appleby, B.Sc., Ph.D.
*Farm Animals and
Sustainable Agriculture*
Katherine Benedict
*Administration, Information
Services, and Technology*
Richard M. Clugston, Ph.D.
Higher Education
Randall Lockwood, Ph.D.
Research and Educational Outreach
Robert G. Rupp, Ph.D., SPHR
Human Resources and Education
Melissa Shuch Rubin, Esq.
Field and Disaster Services
Martin L. Stephens, Ph.D.
Animal Research Issues
Richard W. Swan, Jr.
Investigative Services

DIRECTORS

Patricia Marks Asip
Peter A. Bender
Donald W. Cashen, Ph.D.
Anita W. Coupe, Esq.
Judi Friedman
Alice R. Carey
Jennifer Leaning, M.D.
Amy Freeman Lee, Litt. D.
Franklin M. Loew, D.V.M.
Eugene W. Lorenz
Jack W. Lyman
William F. Mancuso
Joan C. Martin-Brown
Patrick L. McDonnell
Judy J. Peil
Joe Ramsey, Esq.
Jeremy O. Rose
James D. Ross, Esq.
Marilyn G. Seyler
Maurice F. Strong, P.C., C.C., LL.D.
John E. Tait
David O. Wiebers, M.D.
Marilyn E. Wilhelm
K. William Wiseman
John A. Hoyt
President Emeritus
Murdough Stuart Madden, Esq.
Vice President/Senior Counsel

HCD in general consultation with
the Economic and Social Council
of the United Nations

Printed on recycled paper

beneficial effects greatest in poor sanitary conditions.¹ One company's experience with raising broiler chickens without antimicrobials, for growth promotion or therapy, found that this was readily achieved when more attention was paid to ensuring proper ventilation, litter quality, and appropriate densities of bird populations, among other management changes.² Some evidence suggests that immune system stimulation results in reduced growth rates, and feeding antimicrobials allows the producer to realize growth rates similar to those of animals that are minimally stressed and nonmedicated.³

Effective antimicrobials are a most precious tool that we must preserve for treating sick animals *and* sick people. They should not be used in place of proper sanitation and providing animals with adequate space.

Intensive production systems do not account for many basic needs of farm animals. Confined in these quarters, they are unable to perform adaptive behaviors like isolating themselves from others when sick or thermoregulatory efforts such as gathering bedding for warmth, moving away from cold drafts, or wallowing in mud to cool down. Barren and crowded conditions can also be a significant source of stress. Stress can result in injurious behavior and reduced immune competence. Furthermore, research indicates that intense selection for high productivity can mean selection against disease resistance.⁴ These conditions and practices seemingly further the dependence of intensive animal production on antimicrobials.

It is vital to ask why antimicrobials are used in animal agriculture. The answers demonstrate that considerable reductions can and must be made. Industry should not be allowed to use these drugs as a band-aid for poor management. Better husbandry that reduces the need for antimicrobials is necessary. Several European countries are moving in this direction, such as Sweden, where broilers have been raised successfully for a number of years without the use of subtherapeutic antimicrobials. The health of broilers there has been maintained by using good

Promoting the protection of all animals

2100 L Street, NW, Washington, DC 20037 ■ 202-452-1100 ■ Fax: 202-778-6132 ■ www.hsus.org

THE HUMANE SOCIETY OF THE UNITED STATES

OFFICERS

David O. Wiebers, M.D.
Chairman of the Board
Anita W. Coupe, Esq.
Vice Chairman
Anny Freeman Lee, LL.D.
Secretary
Paul G. Irwin
President, CEO
G. Thomas Waite III
Treasurer, CFO
Patricia A. Forhan
Executive Vice President
Roger A. Kunkler, Esq.
Vice President/General Counsel

STAFF VICE PRESIDENTS

Martina C. Armstrong
Senior Vice President
Companion Animals
and Equine Protection
John W. Grandy, Ph.D.
Senior Vice President
Wildlife Programs
Wayne Paschke
Senior Vice President
Communications and
Government Affairs
Andrew N. Rowan, Ph.D.
Senior Vice President
Research, Education, and
International Issues
Michael C. Appleby, B.Sc., Ph.D.
Farm Animals and
Sustainable Agriculture
Katherine Benedict
Administration, Information
Services, and Technology
Richard M. Clugston, Ph.D.
Higher Education
Randall Lockwood, Ph.D.
Research and Educational Outreach
Robert G. Rupp, Ph.D., SPHR
Human Resources and Education
Mekesa Seloe Rubin, Esq.
FBI and Disaster Services
Marion L. Stephens, Ph.D.
Animal Research Issues
Richard W. Swann Jr.
Investigative Services

DIRECTORS

Patricia Mares Asp
Peter A. Bender
Donald W. Cashen, Ph.D.
Anita W. Coupe, Esq.
Judi Friedman
Alice R. Garey
Jennifer Learning, M.D.
Anny Freeman Lee, LL.D.
Franklin M. Lowy, D.V.M.
Eugene W. Lorenz
Jack W. Lyman
William F. Mancuso
Joan C. Martin-Brown
Patrick L. McDonnell
Judy J. Peil
Joe Ramsey, Esq.
Jeffery O. Ross
James D. Ross, Esq.
Marilyn G. Seyler
Maurice F. Strong, PC, C.C., LL.D.
John E. Tatt
David O. Wiebers, M.D.
Marilyn E. Wilhelm
K. William Wessman
John A. Hoyt
President Emeritus
Maraugha Stuart Madden, Esq.
Vice President/Senior Counsel

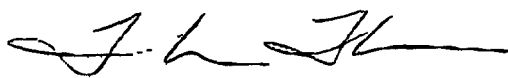
NCO in general consultative status
with the Economic and Social Council
of the United Nations

Printed on recycled paper

sanitation, environmental controls, and reduced stocking densities.⁵ Indeed, within the USA there are producers that raise animals in a humane and sustainable manner with little or no use of antimicrobials.

We would like to thank the FDA for considering this important issue and for this opportunity to comment.

Sincerely,



Tamiko J. Thomas, M.Sc.
Animal Scientist-Program Manager
Farm Animals and Sustainable Agriculture

References:

1. National Research Council, 1999. The Use of Drugs in Food Animals: Benefits and Risks. Washington, DC. National Academy Press
2. Muirhead, S. 2002. Antibiotic Use is Main topic of discussion among vet groups. Feedstuffs October 21, 2002. 1&4
3. Prescott, J.F., Baggot, J.D., and Walker, R.D. (ed) 2000. Antimicrobial Therapy in Veterinary Medicine. Ames, Iowa
4. Cook, M.E. 2000. Interplay of management, microbes, genetics, immunity affects animal growth, development. Feedstuffs January 3, 2000. 11-12
5. Whitehead, C.C. 2002. Nutrition and Poultry Welfare. World's Poultry Science Journal, 58:349-356

Promoting the protection of all animals

2100 L Street, NW, Washington, DC 20037 • 202-452-1100 • Fax: 202-778-6132 • www.hsus.org

THE HUMANE SOCIETY OF THE UNITED STATES™

2100 L Street, NW, Washington, DC 20037
202-452-1100 • www.hsus.org

Date: NOV. 26/02

of Pages: 4

To: FDA-DOCKET NO. 98D-1146

From: TAMIKO THOMAS

Fax # sent to: 301-827-6870

Fax # sent from: 301/258-3078

Note:

Please add to Docket No. 98D-1146.

Originals in the mail: ____ Yes ____ No
If there are any problems receiving this fax, Please Call:

(202) 452-1100